UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/382,088	08/24/99	HOPE	E	A-67031-1/RF

HM12/0829
FLEHR HOHBACH TEST ALBRITTON & HERBERT
FOUR EMBARCADERO CENTER
SUITE 3400
SAN FRANCISCO CA 94111-4187

EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	8

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/382,088	Hope et al.
Examiner	**Group Art Unit**
DeCloux, Amy	1644

☒ Responsive to communication(s) filed on *Apr 17, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-42* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-42* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, drawn to a method of reducing immune-mediated damage to cells using HSP47-related polypeptide, classified in Class 424, subclass 185.1,

II. Claims 8-15, drawn to a method of reducing immune-mediated damage to cells using HSP47 polypeptide, classified in Class 424, subclass 185.1,

III. Claims 16-18, drawn to a method of reducing immune-mediated damage to cells using brefeldin, classified in Class 514, subclass 450,

IV. Claims 19-25, drawn to a method of reducing immune-mediated damage to cells using nucleic acid expressing HSP47-related polypeptide, classified in Class 514, subclass 44,

V. Claims 26-29, drawn to a method of adoptive immunotherapy to treat cancer with cultured T cells and an immunoprotective agent consisting of HSP47-related protein and brefeldin, classified in Class 424, subclasses 93.7, 184.1 and 185.1, and Class 514, subclass 450,

VI. Claims 30-31, drawn to a method for identifying cells which bind to a polypeptide, classified in Class 435, subclass 4,

VII. Claims 32-34, drawn to a composition comprising HSP47-related polypeptide, classified in Class 514, subclass 2,

VIII. Claim 35, drawn to an HSP47-related polypeptide in combination with a cell, tissue or organ, classified in class 514, subclass 2, and class 424, subclass 93.7,

IX. Claim 36, drawn to an antibody, classified in class 530, subclass 387.9,

X. Claim 37, drawn to an anti-idiotypic antibody, classified in class 530, subclass 387.2,

XI. Claims 38-40, drawn to a vector encoding human HSP47 polypeptide, a host cell, and a process for producing said polypeptide, classified in class 536, subclass 23.5, and class 435, subclas 320.1,

XII. Claims 41-42, drawn to a chimeric molecule comprising an HSP47 molecule, classified in Class 424, subclass 192.1.

2. Inventions I-VI are different methods. The methods of Inventions I-IV are drawn to a method of reducing immune-mediated damage, but they use different components such as an HSP47-related polypeptide, HSP47 polypeptide, brefeldin, and a nucleic acid expressing HSP47-related polypeptide, respectively. The methods of Inventions V and VI have distinct endpoints and process steps, encompassing adoptive immunotherapy and identifying cells which bind to a polypeptide, respectively, and these endpoints and process steps are distinct from those of Inventions !-IV. Therefore, Inventions I-VI are patentably distinct.

3. Inventions VII-XII are different products. The products of Inventions VII-XII differ with respect to their biochemical structure and properties, being drawn to HSP47-related polypeptide, an HSP47-related polypeptide in combination with a cell tissue or organ, an antibody, an anti-idiotypic antibody, a vector, and a chimeric HSP47 molecule. Therefore, Inventions VII-XII are patentably distinct.

4. Invention VII and Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the HSP47-related polypeptide, can be used as an antigen in methods to produce an antibody against said polypeptide.

5. Because Inventions I-XII are distinct for the reasons given above, and they have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. If Group I or IV-VIII is elected, the applicant is further required under 35 U.S.C. 121;

A) To elect a **specific HSP47-related polypeptide.**

7. If Group I-IV is elected, the applicant is further required to:

A) To elect if contact is **in vivo or in vitro,**

B) To elect a **specific cause of the immune mediated damage**, such as autoimmune disease, or graft vs host or host vs graft, as recited in claims 6, 15, 17 and 24.

8. The species are distinct each from the other for the following reasons:

A) Each HSP47 related polypeptide has different biochemical structure,

B) in vitro and in vivo methods encompass different process steps and endpoints.

C) Autoimmune disease, graft vs host disease, host vs graft disease are distinct disorders which cause distinct immune mediated damage.

9. Applicant is required, in response to this action, to elect a specific species to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected species, including

any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

10 Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. The following claim(s) are generic: claims 1, 8, 16, 19, 26, 30, 32 and 35, for example.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with *37 C.F.R. § 1.48(b)* if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under *37 C.F.R. § 1.48(b)* and by the fee required under *37 C.F.R. § 1.17(h).*

15. A telephone call to request an oral election was not made due to the complexity of the restriction.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
August 28, 2000

PHILLIP GAMBEL
Primary
PHILLIP GAMBEL
PATENT EXAMINER
GROUP 1600
TECH CENTER 1600
8/28/00